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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,895	08/06/2003	Philippe Despres	241161US0DIV	7352
22850	7590	02/21/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			CHEN, STACY BROWN	
		ART UNIT	PAPER NUMBER	
		1648		

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/634,895	DESPRES ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 December 2005.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3-7,10-14,17-23 and 25-65 is/are pending in the application.
- 4a) Of the above claim(s) 3-7,10-14,17-23,25-41,44-49 and 51-65 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 42,43 and 50 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 August 2003 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/6/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment</u> .   |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group VI, claims 42, 43 and 50, is acknowledged. Applicant argues that searching all of the claims of the invention would not be burdensome. In response to this argument, the restriction requirement establishes the distinctness of the inventions and the reasons why a search would be burdensome. Applicant has not specifically addressed any of the particular reasons set forth in the restriction requirement. Applicant also states that if the product claims are allowable, methods relating to the allowable product may be rejoined. In response, the Office recognizes Applicant's right to rejoinder should the elected product claims be found allowable, and if the appropriate method claims relating to such an allowable product are amended during prosecution to correspond with the allowable product.

Therefore, the restriction is deemed proper and made FINAL.

Claims 3-7, 10-14, 17-23 and 25-65 are pending. Claims 3-7, 10-14, 17-23, 25-41, 44-49 and 51-65 are withdrawn from consideration being drawn to non-elected subject matter. Claims 42, 43 and 50 are under examination.

#### ***Specification***

2. The first line of the first page of the specification should be updated to reflect the current status of parent application, USSN 09/881,710, now US Patent 6,673,895.

#### ***Claim Objections***

3. Claim 50 is objected to for improper grammar in the phrase, "a physiological acceptable carrier", which should be, "a physiologically acceptable carrier". Correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42, 43 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites, "An isolated polypeptide of the sequence in SEQ ID NO: 3". The scope of the claim and its dependent claims 43 and 50, is not clear because the claim language could read on fragments of SEQ ID NO: 3. If Applicant intends to claim the full-length sequence of SEQ ID NO: 3, then the following language is suggested for clarity: "An isolated polypeptide comprising SEQ ID NO: 3". Without further explanation in the specification, the claim language fails to convey the metes and bounds of the invention.

Claims 43 and 50 recite the limitation "the peptide of Claim 42". There is insufficient antecedent basis for this limitation in claim 42, which refers only to a polypeptide, not a peptide. Correction is required.

5. Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 42 is drawn to an isolated polypeptide comprising SEQ ID NO: 3, wherein said peptide

(polypeptide) induces apoptosis in a cell. The claim encompasses a large genus of cells that are susceptible to apoptosis.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only information provided about the cell is that it is susceptible to apoptosis. However, there is no explanation of how the claimed polypeptide induces apoptosis in the cell, so there is inadequate structure/function correlation. While Applicant has suggested that cancer cells may be a potential target, there are many types of cancer cells. Without further disclosure, Applicant has failed to adequately demonstrate possession of the large genus of cells that are susceptible to apoptosis when somehow contacted with SEQ ID NO: 3. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. It is suggested that the intended function (or inherent function) recited in claim 43 be removed to overcome this rejection.

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhamarapravati *et al.* (WO 96/40933, “Bhamarapravati”). The claims are drawn to an isolated polypeptide comprising SEQ ID NO: 3. A reasonable interpretation of the claim language suggests that fragments of SEQ ID NO: 3 are also an embodiment of the invention (see 112, 2<sup>nd</sup> paragraph rejection above). The polypeptide is capable of inducing apoptosis in a cell.

Bhamarapravati teaches the use of infectious Dengue 2 virus PDK-53 as a quadrivalent vaccine. Particularly, a deduced amino acid fragment of Bhamarapravati’s SEQ ID NO: 2 (amino acids 211-240) shares 100% sequence identity to Applicant’s SEQ ID NO: 3 (see attached Sequence Alignment). While the sequence of Bhamarapravati is larger than Applicant’s (3,391 amino acids compared to 30 amino acids), the open claim language reasonably encompasses polypeptides of greater length. Since the structure of Bhamarapravati’s polypeptide meets the limitations of the instant claims as written, any inherent functions of the claimed polypeptide are expected to be present in Bhamarapravati’s polypeptide. Therefore, claims 42 and 43 are anticipated by the prior art.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 42, 43 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhamarapravati *et al.* (WO 96/40933, “Bhamarapravati”). The claims are drawn to an isolated

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polypeptide comprising SEQ ID NO: 3. A reasonable interpretation of the claim language suggests that fragments of SEQ ID NO: 3 are also an embodiment of the invention (see 112, 2<sup>nd</sup> paragraph rejection above). The polypeptide is capable of inducing apoptosis in a cell. Also claimed is a composition comprising SEQ ID NO: 3, or sequence within SEQ ID NO: 3, along with a physiologically acceptable carrier.

Bhamarapravati teaches the use of infectious Dengue 2 virus PDK-53 as a quadrivalent vaccine. Particularly, a deduced amino acid fragment of Bhamarapravati's SEQ ID NO: 2 (amino acids 211-240) shares 100% sequence identity to Applicant's SEQ ID NO: 3 (see attached Sequence Alignment). While the sequence of Bhamarapravati is larger than Applicant's (3,391 amino acids compared to 30 amino acids), the open claim language reasonably encompasses polypeptides of greater length. Since the structure of Bhamarapravati's polypeptide meets the limitations of the instant claims as written, any inherent functions of the claimed polypeptide are expected to be present in Bhamarapravati's polypeptide.

While Bhamarapravati suggests the use of the claimed polypeptide in a vaccine, no specific mention of a physiologically acceptable carrier is made. However, one of ordinary skill in the art would have been motivated to use a physiologically acceptable carrier along with the administration of Bhamarapravati's composition. One would have had a reasonable expectation of success that a physiologically acceptable carrier would have worked with Bhamarapravati's composition because the polynucleotide and encoded polypeptide must be administered in some sort of vehicle, even water. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

*Conclusion*

8. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
Stacy B. Chen  
February 16, 2006





07-JUN-1995; 95US-00483292.

Sequence 3391 AA: